

## MEDICARE NATIONAL COVERAGE ISSUES MANUAL

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### 35-30.1 STEM CELL TRANSPLANTATION

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. The transplant can be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

#### ALLOGENEIC

- A. Allogeneic Stem Cell Transplantation.--Allogeneic stem cell transplantation (ICD-9-CM procedure codes 41.02, 41.03, 41.05, and 41.08) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.
1. Covered Conditions.--The following uses of allogeneic bone marrow transplantation are covered under Medicare:
    - Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91), or aplastic anemia (ICD-9-CM codes 284.0 through 284.9) when it is reasonable and necessary; and
    - Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2), and for the treatment of Wiskott - Aldrich syndrome (ICD-9-CM 279.12).
  2. Non-covered Conditions.--Effective May 24, 1996, allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.0 and 238.6).

#### AUTOLOGOUS

- B. Autologous Stem Cell Transplantation (Effective for Services Performed on or After 04/28/89).--Autologous stem cell transplantation (ICD-9-CM procedure codes 41.01, 41.04, 41.07, and 41.09) is a technique for restoring stem cells using the patient's own previously stored cells.
1. Covered Conditions.--Autologous stem cell transplantation (ICD-9-CM codes 41.01, 41.04, 41.07, 41.09, CPT-4 code 38241) is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:
    - Acute leukemia in remission (ICD-9-CM codes 204.01, lymphoid; 205.01, myeloid; 206.01, monocytic; 207.01, acute erythremia and erythroleukemia; and 208.01 unspecified cell type) who have a high probability of relapse and who have no human leucocyte antigens (HLA) matched;

- Resistant non-Hodgkin's lymphomas (ICD-9-CM codes 200.00-200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88, and 202.90-202.98) or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma (see ICD-9-CM Neoplasm by site, malignant); or
- Advanced Hodgkin's disease (ICD-9-CM codes 201.00-201.98) who have failed conventional therapy and have no HLA-matched donor;

Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients that fit the following requirement:

- a. Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50 percent decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and
- b. Adequate cardiac, renal, pulmonary, and hepatic function.

**NOTE:** Tandem transplantation for multiple myeloma remains non-covered.

2. Non-covered Conditions.--Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
- Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);
- Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0-199.1);
- Up to October 1, 2000, multiple myeloma;

Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;

Effective October 1, 2000, non-primary (AL) amyloidosis (ICD-9-CM 277.3);

Effective October 1, 2000, primary (AL) amyloidosis (ICD-9-CM 277.3) for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.